

Claims 1-14, 23, and 25-31 are rejected under 35 U.S.C. §103(a) for alleged obviousness in view of each of U.S. Patent Nos. 5,780,497 and U.S. 5,880,137, and European Patent Applications EP0802184A1 and EP0802183, each to Miller et al. (collectively, "the Miller references"), in view of Sawicka, J., Pharmazie 1991, vol. 46 page 519-521 (hereinafter "the Sawicka reference"). Applicants respectfully request reconsideration of the rejection, as the cited art, either alone or in combination, neither discloses nor suggests the claimed invention.

The Office Action asserts that the Miller references disclose active substituted indole compounds that are useful in pharmaceutical compositions containing a pharmaceutically acceptable carrier or excipient to be administered to an animal. The Office Action further alleges that the Miller et al. references broadly teach a pharmaceutical formulation comprising a filler and disintegrant components, a wetting agent, a lubricant and a glidant. The Office Action further alleges that the Sawicka reference teaches that adding an antioxidant to a pharmaceutical composition well known in the art, and that the stability of a formulation may be increased by addition of an antioxidant. Office Action at page 3.

Significantly, however, the Office Action admits that:

The prior art does not expressly disclose the employment of the specific range amounts of a filler and disintegrant components, a wetting agent, a lubricant, and a glidant in a pharmaceutical composition herein. The prior art does not expressly disclose the pharmaceutical composition herein further comprising an antioxidant."

Office Action at page 3. Nevertheless, the Office Action asserts that it would have been obvious

...to determine the specific range amounts of a filler and disintegrant components, a wetting agent, a lubricant, and a glidant in a pharmaceutical composition herein, and to further add an antioxidant to a pharmaceutical composition herein.

Office Action at page 3.

Applicants respectfully disagree with the Office Action.

In establishing a *prima facie* case of obviousness under 35 U.S.C. §103, it is incumbent upon the Office to provide a reason why one of ordinary skill in the art would have been led to modify a

prior art reference or to combine reference teachings to arrive at the claimed invention. *Ex parte Clapp*, 227 U.S.P.Q. 972 (Bd. Pat. App. Int. 1985). To this end, the requisite motivation must stem from some teaching, suggestion or inference in the prior art as a whole or from the knowledge generally available to one of ordinary skill in the art, and not from applicant's disclosure. See for example, *Uniroyal Inc. v. Rudkin-Wiley Corp.*, 5 U.S.P.Q.2d 1434 (Fed. Cir. 1988); and *Ex parte Nesbit*, 25 U.S.P.Q.2d 1817, 1819 (Bd. Pat. App. Int. 1992). In this respect, the following quotation from *Ex parte Levengood*, 28 U.S.P.Q.2d 1300, 1302 (Pat. Off. Bd. App. 1993), is noteworthy:

Our reviewing courts have often advised the Patent and Trademark Office that it can satisfy the burden of establishing a *prima facie* case of obviousness only by showing some objective teaching in either the prior art, or knowledge generally available to one of ordinary skill in the art, that "would lead" that individual "to combine the relevant teachings of the references." ... Accordingly, an examiner cannot establish obviousness by locating references which describe various aspects of a patent applicant's invention without also providing evidence of the motivating force that would **impel** one skilled in the art to do what the patent applicant has done. (citations omitted; emphasis added)

Significantly, the Office Action identifies no "motivating force" that would "impel" persons of ordinary skill to modify the respective teachings of the cited references and achieve the claimed invention.<sup>1</sup> Rather, as best understood, the Office Action appears to assert that the cited art renders the present claims obvious because the constituent components of the composition are known, and determination of the claimed amounts of those components only requires routine skill. However, motivation to modify or combine the prior art must be derived from objective teachings, not mere speculation as to what those of ordinary skill in the art might do. See *In re Laskowski*, 871 F.2d 115, 117, 10 U.S.P.Q.2d 1397, 1399 (Fed. Cir. 1989) ("[t]he mere fact that the prior art could be so modified would not have made the modification obvious **unless the prior art suggested the desirability of the modification**") (citations omitted; emphasis added). As the Office Action admits, the claimed ranges of components recited in the present claims are not disclosed in the cited

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<sup>1</sup> Indeed, Applicants do not find any specific reference to the terms "glidant" or "wetting agent" in the Miller references.

art. And the Office Action has not pointed to any suggestion in the art to modify the teachings thereof to achieve the invention recited in the claims. Rather, the Office Action appears to assert that motivation arises from general desire for “optimization” of amounts of pharmaceutical compositions. However, this is not the “motivating force” that would “impel” persons of ordinary skill to modify the respective teachings of the cited references and achieve the claimed invention. Rather, the Office Action appears to have applied an “obvious to try” standard, which is not permitted. *See In re Farrell*, 7 U.S.P.Q.2d 1673, 1681 (Fed. Cir. 1988).

The Sawicka reference merely discusses the influence of antioxidants on the stability of cholecalciferol (vitamin D). The Sawicka reference does not disclose or suggest the range of components recited in the present claims, and also fails to suggest using its antioxidants in such compositions. Accordingly, it can be seen that the Sawicka reference fails to cure the deficiencies of the Miller references, and that the combination of the cited art simply does not produce the claimed invention. Moreover, even assuming that the cited art provided legally sufficient motivation to achieve the invention of the present claims, (and it does not), there is no suggestion or evidence in the cited art that employing such antioxidants useful for cholecalciferol formulations would be successful in the claimed compositions.

Inasmuch as the cited art fails to teach or suggest the invention of the claims, Applicants respectfully assert that the Office Action has failed to establish a *prima facie* case of obviousness. Accordingly, Applicants respectfully request withdrawal of this rejection.

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Applicants believe the claims are in condition for allowance and an early Notice of Allowance on the remaining claims is earnestly solicited. Applicant invites the Examiner to contact the undersigned at (215) 665-5548 to clarify any unresolved issues raised by this response

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Michael P. Straher", with a long horizontal flourish extending to the right.

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